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Exhibit 2  
US App. Ser. No. 09/905,592  
Page 1 of 6

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/142,305	09/10/99	OZAWA	K 50026/012001

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HM22/0621

EXAMINER

SISSON, B

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

06/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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**Office Action Summary**

Application No.

09/142,305

OZAWA ET AL.

Examiner

Bradley L. Sisson

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-17 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

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***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, drawn to a fusion protein.

Group II, claim(s) 5 and 8-14, drawn to a vector; claims 6 and 15, drawn to a cell comprising the vector; and claim 17 drawn to a kit.

Group III, claim(s) 7 and 16, drawn to a method for selectively proliferating a cell.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Groups I and II are drawn to products having different composition and properties. Also, the method of Group III does not require the product of Group I.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephanie Zitomer can be reached on (703) 308-3985. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson  
Primary Examiner  
Art Unit 1655

BLS  
June 20, 2001

Claims

- Sub A2
1. A fusion protein comprising (a) a ligand-binding domain, (b) a domain that associates when a ligand binds to the domain of (a), and (c) a domain comprising a cytokine receptor or a part thereof that imparts proliferation activity to a cell upon the association.
  2. The fusion protein of Claim 1, wherein the "domain comprising a cytokine receptor or a part thereof that imparts proliferation activity to a cell upon the association" is derived from a G-CSF receptor.
  3. The fusion protein of Claim 1, wherein the "ligand-binding domain" is derived from a steroid hormone receptor.
  4. The fusion protein of Claim 3, wherein the steroid hormone receptor is an estrogen receptor.
  5. A vector comprising a gene encoding the fusion protein of Claim 1.
  6. A cell carrying the vector of Claim 5.
  7. A method for selectively proliferating the cell of Claim 6, which comprises exposing the cell of Claim 6 to a ligand capable of acting on the "ligand-binding domain" of the fusion protein of Claim 1.
  8. A vector comprising a desired exogenous gene and a gene encoding a fusion protein comprising (a) a ligand-binding domain, (b) a domain that associates when a ligand binds to the domain of (a), and (c) a domain that imparts proliferation activity to a cell upon the association.
  9. The vector of Claim 8, wherein the "domain that imparts proliferation activity to a cell upon the association" is derived

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from a cytokine receptor.

10. The vector of Claim 9, wherein the cytokine receptor is a G-CSF receptor.

11. The vector of Claim 8, wherein the "ligand-binding domain" is derived from a steroid hormone receptor.

12. The vector of Claim 11, wherein the steroid hormone receptor is an estrogen receptor.

13. The vector of Claim 8, wherein the "gene encoding a fusion protein" and the "exogenous gene" are located on the same molecule.

14. The vector of Claim 8, wherein the "gene encoding a fusion protein" and the "exogenous gene" are located on separate molecules.

15. A cell carrying the vector according to any one of claims 8 to 14.

16. A method for selectively proliferating the cell of Claim 15, which comprises exposing the cell of Claim 15 to a ligand capable of acting on the "ligand-binding domain" of the fusion protein encoded by the gene contained in the vector of Claim 8.

17. A kit comprising (a) the vector of Claim 5 or Claim 8, and (b) a ligand capable of acting on the "ligand-binding domain" of the fusion protein encoded by the gene contained in the vector.

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